510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k041926

B. Purpose for Submission:

Clearance of new calibrator for a device

C. Measurand:

Low and High Density Lipoproteins (LDL and HDL)

D. Type of Test:

Calibrator

E. Applicant:

Diagnostic Chemicals Limited

F. Proprietary and Established Names:

HDL/LDL-Advance Calibrator

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1150, Calibrator

2. Classification:
   Class II

3. Product code:
   JIX, Calibrator, multi-analyte mixture

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   HDL/LDL-Advance Calibrator is used to calibrate HDL Cholesterol and LDL Cholesterol Assays in serum. HDL is high density lipoprotein and LDL is a low

density lipoprotein.

2. Indication(s) for use:

   see intended use above

3. Special conditions for use statement(s):

   For in vitro diagnostic use

4. Special instrument requirements:

   See k041927 and k041928 for information on the HDL and LDL assays

I. Device Description:

The HDL/LDL-Advance Calibrator is provided lyophilized (to be reconstituted with deionized water). For more information on traceability and matrix, see Traceability below.

All human source material was tested and found non-reactive for HBsAg, HCV, and HIV-1/2 by an FDA-approved method.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Multi Analyte Calibrator

2. Predicate 510(k) number(s):
   k011658

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Calibration of assays	
contents	4 x 2 mL lyophilized human serum	3 x 1 mL lyophilized human serum

Differences		
Item	Device	Predicate
analytes	HDL and LDL	HDL, LDL, and apolipoprotein

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Not applicable. This submission is for clearance of a calibrator.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The calibrator contains HDL and LDL in a human serum matrix. The calibrators are purchased from a commercial source and distributed by the sponsor. Calibrators are included with the assays (see k041927 and k041928 for information on the assays).

The HDL is added gravimetrically to the calibrator from a certified primary material. LDL is added from an in-house human serum pool. The values are assigned by repeated testing by commercially available assays.

Stability testing protocols and acceptance criteria were reviewed and found acceptable. After reconstitution, the calibrator is stable for 7 days at 2 – 8˚C.

   d. Detection limit:

   Not applicable

   e. Analytical specificity:

   Not applicable

   f. Assay cut-off:
   Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*

      Not applicable

   b. *Matrix comparison:*

      Not applicable

3. Clinical studies:
   a. *Clinical Sensitivity:*
      Not applicable

   b. *Clinical specificity:*
      Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):
      Not applicable

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.